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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,576	07/06/2001	Andreas Rick	14XZ00120	4078

7590 01/30/2003

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EXAMINER

BARBER, THERESE

ART UNIT PAPER NUMBER

2882

DATE MAILED: 01/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/900,576

Applicant(s)

RICK ET AL.

Examiner

Therese Barber

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 06 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 41 is/are allowed.
- 6) ☐ Claim(s) 1-4, 9, 21, and 25-40 is/are rejected.
- 7) ☐ Claim(s) 5-8, 10-20 and 22-24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Objections

2. Claims 1, 2, 4, 6, 9-24, 26-28, 30, 32, 34, 39 and 40 are objected to because of the following informalities:
 3. Regarding claim 1, delete the phrase "has crossed" and insert the term "penetrate". Practitioners in the art would contend that the x-ray beam does not cross an organ but that the x-ray beam would penetrate the organ.
 4. Regarding claim 2, the limitation is "a first image is taken before the injection of the contrast medium". However, claim 2 depends upon independent claim 1 that states "a representative image of the contrast from the tissues of the organ is produced from the plurality of digital images"; thus, it is contended that the representative image is the first image because it has been cited in the independent claim.
 5. Regarding claim 4, the limitation is "at least one second image is taken after injection of the contrast medium". However, the examiner contends that claim limitation is improper because claim 2 states that a first image is taken before the injection of the contrast medium and claim 1 states that a representative image of the contrast medium from the plurality of digital

images is the second image; therefore, how can "a second image" be taken if at least two images have taken?

6. Regarding claim 6, the limitation is "at least one second image is taken during a phase of heightened attenuation due to the contrast medium". However, the examiner contends that claim limitation is improper because claim 2 states that a first image is taken before the injection of the contrast medium and claim 1 states that a representative image of the contrast medium from the plurality of digital images is the second image; therefore, how can "a second image" be taken if at least two images have taken?

7. Regarding claims 9-13, the limitation of "the second images are equally distributed in time" is vague and indefinite. One could assume that the instant invention is implying that only the second image has the same time interval? In addition, these claims are dependent upon claims, which state "at least one second image" which implies a single second image.

8. Regarding claims 13-17, the limitation of "the second images are taken at shorter intervals ... than after the phase" is vague and indefinite. These claims are dependent upon claims, which state "at least one second image".

9. Regarding claims 13-17, line 3, insert the phrase "of heightened attenuation" after the term "phrase".

10. Regarding claims 18-20, line 3, insert the phrase "attenuation" before the term "phrase".

11. Regarding claim 19, the claim is depended upon claim 6, however, the examiner contends that claim limitation is improper because claim 2 states that a first image is taken before the injection of the contrast medium and claim 1 states that a representative image of the contrast

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medium from the plurality of digital images is the second image; therefore, how can "a second image" be taken if at least two images have taken?

12. Regarding claims 21-24, the limitation of "in which the first image is subtracted from each of the second images" is vague because these claims depended upon claims that imply that a single second image has been taken.

13. Regarding claims 26-28, the claims recite the limitation "subtracted images are filtered spatially" in claims 27, 28, and 29. There is insufficient antecedent basis for this limitation in these claims. In addition, the claims are improper dependent claims.

14. Regarding claim 30, the term "mammothography" should be changed to the term "mammography".

15. Regarding claims 32 and 34, the limitations of "a gray level of the image is proportional to a quantity of the contrast medium per unit surface of the image" and "wherein a gray level of the image depends on the density of contrast medium in the organ" are vague and indefinite. Are the applicants implying that only the second image will have a gray scale level that is proportional to the contrast medium?

16. Claims 39 and 40 are objected to under 37 CFR 1.75(c) as being in improper form because of the claims dependency on claims 1-40. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 1-4 rejected under 35 U.S.C. 102(b) as being anticipated by Hunt (USPN 4,335,427).

19. Regarding claims 1 and 3, Hunt discloses a radiological examination (col. 2, lines 27-30 and 50-60) comprised of injecting a contrast medium into an organ (col. 3, lines 22-26); emitting an x-ray beam in the direction of the organ (cols. 1, lines 49-54; 2, lines 50-54); taking a plurality of digital images after the x-ray beam has penetrated the organ (col. 3, lines 38-41); calculating a representative image of the contrast produced in the organ from the digital images (col. 3, lines 44-48); and taking an image after the injection of the contrast medium (col. 3, lines 26-29).

20. Regarding claims 2 and 4, Hunt discloses taking an image of the organ before the injection of the contrast medium (col. 3, lines 22-26) and an image after the injection of the contrast medium (col. 4, lines 38-51).

21. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown (USPN 5,459,769).

22. Regarding claims 1 and 3, Brown discloses a radiological examination of an organ comprised of injecting a contrast medium into an organ (col. 4, lines 31-33); emitting an x-ray beam in the direction of the organ (col. 3, lines 22-29); taking a plurality of digital images after

the x-ray beam has penetrated the organ (col. 3, lines 38-41); calculating a representative image of the contrast produced in the organ from the digital images (col. 3, lines 44-48); and taking an image after the injection of the contrast medium (col. 4, lines 38-51).

23. Regarding claims 2 and 4, Brown discloses the steps of taking an image of the organ before the injection of the contrast medium (104; col. 4, lines 9-18) and an image after the injection of the contrast medium (col. 4, lines 38-51).

Claim Rejections - 35 USC § 103

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

25. Claims 9, 21, 25-28, 30 and 32-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunt as applied to claims 1 and 3, respectively, further in view of Sharma et al. (USPN 5,596,200).

26. Regarding claims 9, 21, 25-28 and 35-40, Hunt fails to disclose that the images are equally distributed in time, the image taken before the contrast medium can be substrated from the composite images, and the substrated images can be filtered spatially.

However, Hunt discloses a radiological examination (col. 2, lines 27-30 and 50-60) comprised of injecting a contrast medium into an organ (col. 3, lines 22-26); emitting an x-ray beam in the direction of the organ (cols. 1, lines 49-54; 2, lines 50-54); taking a plurality of

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digital images after the x-ray beam has penetrated the organ (col. 3, lines 38-41); calculating a representative image of the contrast produced in the organ from the digital images (col. 3, lines 44-48); and taking an image after the injection of the contrast medium (col. 3, lines 26-29).

Sharma discloses a digital x-ray imaging system that utilized semiconductor sensor elements with reduced radiation exposure to the patient, higher sensitivity, improve image resolution, image contrast, color/gray scales (table 1; col. 4, lines 3-37). In addition, Sharma discloses that after the images are taken, the information is sent to a data acquisition/storage device and then to an image processing unit, whereby a variety of image manipulations can occur including attaching gray scales, contrast enhancement and image subtraction (col. 6, lines 51-65). Sharma also discloses that x-ray imaging system can be utilized in exposing a sample such as a breast (col. 2, lines 18-27) will being cost effective (col. 7, lines 3-6). It is well in the art the imaging processing capabilities are constantly improving with the advancement made in computer software and hardware equipment, thereby, it is inherent that computers can be programmed to perform temporal filtering, frame averaging, smoothing and that computers are assembled with large internal storage devices (60 or more GB hard drives); CD drives that utilize disks capable of storing 720 MB of information on one disk; and external storage devices such as ZIP drives.

It would have been obvious to one having ordinary skill in the art at the time the invention was made that the combination of steps as disclosed by Hunt could be utilized in image processing unit of the digital x-ray imaging system as disclosed by Sharma. According, the image processing unit can perform a number of functions that will improve the image resolution,

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thereby, making it easier to pinpoint the location and density of the contrast medium inside an organ.

27. Regarding claims 30 and 32-34, Hunt fails to disclose that the gray level is proportional to the quantity and density of the contrast medium, the range of images that are utilized to form a composite image and the images are from a mammography examination.

However, Hunt discloses a radiological examination (col. 2, lines 27-30 and 50-60) comprised of injecting a contrast medium into an organ (col. 3, lines 22-26); emitting an x-ray beam in the direction of the organ (cols. 1, lines 49-54; 2, lines 50-54); taking a plurality of digital images after the x-ray beam has penetrated the organ (col. 3, lines 38-41); calculating a representative image of the contrast produced in the organ from the digital images (col. 3, lines 44-48); and taking an image after the injection of the contrast medium (col. 3, lines 26-29).

Sharma discloses a digital x-ray imaging system that utilized semiconductor sensor elements with reduced radiation exposure to the patient, higher sensitivity, improve image resolution, image contrast, color/gray scales (table 1; col. 4, lines 3-37). In addition, Sharma discloses that after the images are taken, the information is sent to a data acquisition/storage device and then to an image processing unit, whereby a variety of image manipulations can occur including attaching gray scales, contrast enhancement and image subtraction (col. 6, lines 51-65). Sharma also discloses that x-ray imaging system can be utilized in exposing a sample such as a breast (col. 2, lines 18-27) will being cost effective (col. 7, lines 3-6).

It would have been obvious to one having ordinary skill in the art at the time the invention was made that the combination of steps as disclosed by Hunt could be utilized in image

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processing unit of the digital x-ray imaging system as disclosed by Sharma. According, the processing unit can utilize a gray scale table to map the energy from the x-ray beam and to map the contrast medium with each other, thereby, providing information on the location of the contrast medium in the organ with increased image resolution.

28. Claims 29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunt as applied to claim 1 above, and further in view of Mistretta et al. (USPN 3,854,049).

Regarding claims 29 and 31 Hunt fails to disclose wherein the images are converted into thickness images and the emitting x-ray beam has a maximum intensity for a frequency in the same order as a selected absorption line of the contrast medium.

However, Hunt discloses a radiological examination (col. 2, lines 27-30 and 50-60) comprised of injecting a contrast medium into an organ (col. 3, lines 22-26); emitting an x-ray beam in the direction of the organ (cols. 1, lines 49-54; 2, lines 50-54); taking a plurality of digital images after the x-ray beam has penetrated the organ (col. 3, lines 38-41); calculating a representative image of the contrast produced in the organ from the digital images (col. 3, lines 44-48).

Mistretta discloses wherein variations of the x-ray attenuation coefficient of contrast medium are a function of the x-ray energy (figs. 2-4; col. 5, line 30 to col. 6, line 60). Mistretta illustrates in figure 4, the energy of the x-ray spectra at 65 kVp and its relationship to the contrast medium. In addition, Mistretta illustrates in fig. 5, that tissue thickness is a function of the x-ray energy as it relates to the attenuation coefficient of the contrast medium (col. 7, lines 1-54).

It would have been obvious to one having ordinary skill in the art at the time the invention was made that the combination of steps as disclosed by Hunt could be modified to utilize the relationship between the x-ray attenuation coefficient of the contrast medium, the x-ray energy and variations in thickness of the organ as disclosed by Mistretta. According, the resultant methodology will have improved image resolution of the contrast medium in the images based on the knowing the relationship between x-ray attenuation coefficient of the contrast medium, the x-ray energy and thickness variation

Allowable Subject Matter

29. Claims 5-8, 10-20 and 22-24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten including all of the limitations of the base claim and any intervening claims and overcoming the claim objections.

30. Regarding claims 5-6, 10-11, 14-15, 18, 19 and 22-23, the prior art fails to disclose or to reasonably suggest the specific steps wherein after injecting an organ with contrast medium, an image of the organ is taken during a phase of heightened x-ray attenuation, as set forth in the claimed combination.

31. Regarding claims 7-8, 12, 16, 20 and 24, the prior art fails to disclose or to reasonably suggest wherein after injecting an organ with contrast medium, an image of the organ is taken after a phase of heightened x-ray attenuation, as set forth in the claimed combination.

32. Regarding claims 13 and 17, the prior art fails to disclose or to reasonably suggest the specific steps wherein after injecting an organ with contrast medium, images are taken at shorter intervals wherein after an image is taken at shorter intervals.

33. Claim 41 is allowed.


Regarding claim 41, the prior art fails to disclose or to reasonably suggest the specific steps of examining an organ, wherein after injecting the organ with the contrast medium, an image is taken during or after the attenuation phase of the x-ray beam, in order to determine the quantity of the contrast medium within the organ, as set forth in the claimed combination.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Therese Barber whose telephone number is (703) 306-0205. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Kim can be reached on (703) 305-3492. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-4857 for regular communications and (703) 308-7722 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-4900.

tb 
January 27, 2003

